

DADE

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Interoffice Memorandum

Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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Date of Preparation: 1/29/97

Name of Product: Thyroid Calibrator

FDA Classification Name: Calibrator

Predicate Device: *aca® plus* FT4 Calibrator and *aca® plus* TSH Calibrator

Device Description: The Thyroid Calibrator is a liquid bovine albumin based product. The Level 1 calibrator contains no detectable thyroxine or TSH. Levels 2 through 5 contain thyroxine and human TSH. The kit consists of ten vials; two at each of five levels.

Intended use: The Thyroid Calibrator is intended to be used on the Dimension® RxL clinical chemistry system with the heterogeneous immunoassay module to calibrate the FT4 and TSH methods.


**Comparison to Predicate
Device:**

<u>Item</u>	<u>Thyroid Calibrator</u>	<u>aca® plus FT4 Calibrator</u>	<u>aca® plus TSH Calibrator</u>
Intended Use	Calibrator	Calibrator	Calibrator
Analytes	thyroxine, TSH	thyroxine	TSH
Matrix	bovine albumin	human serum	horse serum
Form	liquid	lyophilized	lyophilized
Volume	2.0 mL per vial	3.0 mL per vial, reconstituted	5.0 mL per vial, reconstituted
Levels	5 levels	3 levels	3 levels

Comments on Substantial

Equivalence: Both the Thyroid Calibrator and the aca® plus FT4 Calibrator are intended to be used as calibrators for free thyroxine methods. Both the Thyroid Calibrator and the aca® plus TSH Calibrator are intended to be used as calibrators for thyroid stimulating hormone methods.

Conclusion: The Thyroid Calibrator is substantially equivalent to the aca® plus FT4 Calibrator and the aca® plus TSH Calibrator for their respective analytes based on the comparison discussed above.



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